

kit 200 as illustrated does not include labels in packaging 210 along with pen 220. Packaging 210 includes first layer 212 and second layer 214. In the embodiment illustrated in FIG. 2, layers 212 and 214 are made from impermeable metal foil or semi-metallic material. Layers 212 and 214 may also be made from any other suitable material that allows for gamma sterilization. Layers 212 and 214 are joined around a peripheral edge such that a hermetically sealed interior space is created for containing pen 220. Layers 212 and 214 may be joined using any suitable conventional joining process including, for example, adhesive, pressing, crimping, melting, and welding. Similar to pen 120 of PAL kit 100, pen 220 may be any pen or writing instrument, such as a fine-tip, permanent ink pen.

[0030] In preparing PAL kit 200 as shown in FIG. 2, pen 220 may be placed in packaging 210. Excess air in the packaging may then be withdrawn by drawing a vacuum on packaging 210. The vacuum may be a relatively low vacuum sufficient to evacuate some or all of the internal air from packaging 210, while minimizing manufacturing losses due to pen failure. PAL kit 200 may then be hermetically sealed and gamma radiated in a process similar to process described in connection with PAL kit 100 above.

[0031] FIG. 3 shows medical kit 250. In this example embodiment, medical kit 250 includes outer packaging 260, PAL kit 200, as discussed above, labels 230 and additional components 240. Packaging 260 includes a first outer layer 262 and a second outer layer 264, first outer layer 262 may be made of semi-permeable material such as Tyvek® or other suitable material to allow gasses to flow in and out without allowing contaminants to penetrate the material, thereby maintaining the sterility of the interior and contents of medical kit 250 after performance of a sterilization process. The material of first outer layer 262 may also allow printing on the surface of first outer layer 262, so that identification and/or instruction to be printed on the packaging. The sealing and printing processes may be performed simultaneously to reduce production time.

[0032] Second outer layer 264 may be made of a non-permeable transparent plastic material or any other suitable material. Second outer layer 264 may have a depression formed in the material to create a pocket or space for PAL kit 200, labels 230, and additional components 240. Similarly, a pocket may be formed in first outer layer 262 or in neither layer, existing only as a space between joined layers 262 and 264.

[0033] First outer layer 262 and second outer layer 264 of packaging 260 may be joined at a periphery to create a hermetically sealed interior pocket capable of holding contents such as PAL kit 200, labels 230, and additional components 240. Such packaging may be multivac blister packaging. Outer layers 262 and 264 may be joined using any conventional joining processes, such as adhesives and welding. In some embodiments, layers 262 and 264 may also be joined to form more than one interior pocket, allowing for production of several packages with continuous sheets of material. In some embodiments, each of the items contained in medical kit 250 may be placed in a separate respective pocket.

[0034] Outer layers 262 and 264 may also be joined such that on at least one side, the joined portion is located in from the edge to provide a user access to grasp outer layers 262 and 264 separately and separate the joined layers. In other embodiments, a periphery of packaging 260 may include a notch to allow the package to be torn open for use.

[0035] In some embodiments, labels 230 may be included inside of PAL kit 200, or may be included both inside PAL kit 200 along with pen 220 and in outer packaging 260, separate from PAL kit 200. Labels 230 may be conventional labels as discussed above with regard to labels 130. Additional components 240 may include any components for any medical kit that may require labeling, such as with a PAL kit, and may be as numerous or as few as desired in the particular medical kit 250. For example, additional components 240 may include a catheter kit including an introducer sheath, syringes, tubing, guidewire, and collection receptacle.

[0036] In preparing medical kit 250 as illustrated in FIG. 3, PAL kit 200, previously sterilized, labels 230, and additional components 240 are placed in outer packaging 260. Outer layers 262 and 264 are then hermetically sealed. Sterilization is then performed on the medical kit 250, such as by EtO sterilization. Because PAL kit 200 includes foil packaging 210, EtO sterilization does not penetrate PAL kit 200, but does sterilize the external surfaces of packaging 210. During the EtO sterilization, EtO gas penetrates through outer layer 262 and seeps through the open lumens of any tubing and other components contained in medical kit 250.

[0037] In some embodiments, medical kit 250 may include PAL kit 100 as described above instead of PAL kit 200.

[0038] FIG. 4 shows a process diagram of process 400 listing some exemplary steps to create a PAL kit. As shown, packaging is provided in box 410. Box 420 includes the step of placing a writing implement in the packaging. The packaging is sealed to contain the writing instrument in box 430, creating a PAL kit. The PAL kit is sterilized in box 440. Thus, a PAL kit may be created by including at least a writing instrument in packaging, sealing the packaging to contain the writing instrument, and sterilizing the PAL kit.

[0039] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A method for packaging a pen, comprising:
 - placing a writing instrument into packaging configured to be sealed such that the writing instrument is contained in a sealed portion of the packaging;
 - sealing the packaging; and
 - sterilizing the writing instrument and the packaging using gamma sterilization, such that all portions of the writing instrument are sterilized.
2. The method of claim 1, wherein the writing instrument is a permanent ink pen.
3. The method of claim 1, wherein the packaging is one of a multivac blister packaging and a foil packaging.
4. The method of claim 1, wherein the writing instrument is non-sterile prior to the sterilizing using gamma sterilization.
5. The method of claim 1, wherein the sealing includes vacuum sealing.
6. The method of claim 1, wherein the packaging is an inner packaging, and wherein the method further comprises the steps of:
 - placing the sealed inner packaging into an outer packaging;
 - placing at least one other item into the outer packaging;